

The Claims Distinguish Patentably
Over the References of Record

Claim 1 calls for placing an indicator on the single use package which holds the powdered composition which forms an antimicrobial decontaminant. While Minerovic discloses such a single use package, it makes no suggestion of placing an indicator on it. Ignacio does not cure this shortcoming. Ignacio suggests placing an indicator on the barrier wrap or packaging around the item to be sterilized (column 9, line 57) but makes no suggestion of placing an indicator on or in the sterilant source. Ignacio is trying to replicate the exposure conditions which the item being sterilized experiences. Placing an indicator in the source is not reasonably expected to replicate the exposure conditions of the item being sterilized. Rather, the antimicrobial concentration at the source will, when initially mixed with water, achieves a substantially higher concentration than is seen by the items being sterilized. That is, the exposure conditions where the powdered composition is dissolved to make the antimicrobial would not be expected to be the same as the full diluted antimicrobial flow in the sterilization chamber around an item to be sterilized. Accordingly, it is submitted that Ignacio provides no motivation to provide an indicator on the single use package for supplying the powdered composition which forms the antimicrobial solution.

Claim 8 calls for the indicator to be on the top cover of the single use package for holding the dry composition. This location solves the problem of determining whether a single use package that is received in the well 16 is a new package or has been used. Ignacio has no recognition of this problem and no suggestion how it might be solved. Indeed, Ignacio makes no suggestion of placing chemical indicators anywhere except with the items being sterilized. Analogously, Ignacio makes no suggestion that a chemical indicator can be used to

indicate whether an antimicrobial agent cup functioned properly.

Claim 15 calls for a color change indicator to be attached to a source of sterilant. In particular, claim 15 claims a package for holding an antimicrobial concentration which forms an antimicrobial solution when mixed with water. As the concentrate is first mixed with water, the concentration will be at its maximum. The concentration will then be diluted as the concentrate becomes mixed with all of the water in the system and distributed throughout the system. Thus, a measure of concentration made at the source of the antimicrobial concentrate will not provide an accurate representation of the exposure conditions to which the sterilized item was exposed. Ignacio does not teach or fairly suggest placing a chemical indicator in a location where those of ordinary skill in the art would expect it to sense significantly different antimicrobial agent concentrations than are seen by the items being sterilized. Accordingly, it is submitted that claim 15 distinguishes patentably and unobviously over the references of record.

Claim 19 calls for a well in which an antimicrobial solution is mixed from an antimicrobial concentrate. Claim 19 further calls for placing an indicator on a portion of the package which supplies the antimicrobial concentrate to the well. Ignacio does not teach or fairly suggest the placement of chemical indicators in areas displaced from the items being sterilized, which areas would see different exposure conditions than the items to be sterilized. To the contrary, the placement of the indicators described in Ignacio at column 9, lines 54-65 all place indicators where they will experience substantially the same exposure conditions (column 7, lines 25-29) as the items being sterilized. Ignacio provides no motivation to provide an indicator at the mixing well where antimicrobial

concentrate is mixed with water to form an antimicrobial solution.

Claim 20 calls for a package for releasing an antimicrobial composition into a flowing liquid. An indicator is placed on the package, which indicator undergoes a color change which varies in accordance with the concentration and duration with which the solution contacts the indicator. Because the indicator is placed at the source of the concentrate, the concentration and duration information to which it is exposed will be different than the concentration and duration characteristics to which the target items are exposed. Ignacio suggests placing an indicator on packaging which holds items that are the recipient of an antimicrobial solution or even placing the indicator in such a package in conjunction with packaged items, all of which are to be the recipient of such fully diluted, antimicrobial solution. Ignacio makes no suggestion of placing an indicator at the package which contains and is the source of the antimicrobial concentrate. Accordingly, it is submitted that claim 20 distinguishes patentably and unobviously over the references of record.

Claim 21 is directed to a method in which water is flowed through a cartridge that contains a composition to form decontaminant solution from the composition and water. The cartridge includes a porous portion which is impregnated with an indicator. The cartridge C of Minerovic does not include an indicator. Ignacio suggests placing indicators near items which are the recipient of use strength decontaminant solutions, but provides no motivation to place an indicator at the source where concentrates reach higher peaks. To the contrary, it is submitted that Ignacio teaches against placing an indicator at the antimicrobial source in favor of placing the indicator in locations where it will experience the same exposure temperature, the same exposure peracid